HHS SBIR RFA-AI-14-049

NOTE: The Solicitations and topics listed on this site are copies from the various SBIR agency solicitations and are not necessarily the latest and most up-to-date. For this reason, you should use the agency link listed below which will take you directly to the appropriate agency server where you can read the official version of this solicitation and download the appropriate forms and rules.

The official link for this solicitation is: http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-14-049.html

Agency:
Department of Health and Human Services

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Solicitation:
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Close Date:
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Topic Number:
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Description:

The SBIR/STTR Programs were recently reauthorized by the United States Congress with the SBIR/STTR Reauthorization Act of 2011(P.L. 112-81). One change that was made to the SBIR program in this reauthorization was the authority for certain participating federal agencies to 'issue a Phase II award to a small business concern that did not receive a Phase I award for that research/research & development. This is a so-called 'Direct-to-Phase II' SBIR award. This authority would permit SBCs to submit Direct-to-Phase-II SBIR applications, if the small business had performed the Phase I stage-type of research through other funding sources. The legislative rationale for permitting the Direct-to-Phase II award is to allow a SBC that has already built a technology prototype and tested its feasibility (i.e. completed Phase-I-type R&D) to move directly into a Phase-II-type R&D that tests the functional viability of the prototype according to scientific methods and potential for commercial development. The Direct-to-Phase-II SBIR mechanism eliminates the need for the SBCs to propose additional small feasibility studies, if the technology is ready for the Phase II stage of development. The Direct-to-Phase II authority is not available to the STTR program.
Purpose

The goal of this FOA is to move commercially-viable diagnostic inventions from the NIAID and NIDDK intramural research laboratories into the marketplace. This FOA solicits Small Business Innovation Research (SBIR) grant applications from Small Business Concerns (SBCs) for projects that further develop and commercialize such inventions. Any project that fits within the NIAID and NIDDK mission

that relies on the use of a NIAID or NIDDK intramural invention included on the list of inventions referenced below, is eligible for this award.

NIDDK's acceptance of Direct Phase II applications is limited to this Funding Opportunity Announcement and is not otherwise applicable for NIDDK SBIR applications.

This FOA will not accept 'regular' Phase II submissions from SBCs that have received a Phase I SBIR or STTR award from NIH or any other agency that participates in the SBIR/STTR programs. For this FOA, it is expected that the technology, prototype, or method will have passed the proof of principle stage and that the product has demonstrated feasibility and supports a Phase II effort. Data or evidence of the capability, completeness of design, and efficacy must be provided in the application, along with the rationale for selection of the criteria used to validate the technology, prototype, or method, similar to a Phase I final report required in standard Phase II applications.

The NIAID Division of Intramural Research (DIR) is a component of NIAID, whose mission is to conduct and support basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. DIR scientists study all aspects of infectious diseases, including the causative agent, vectors, and pathogenesis in human and animal hosts. Clinical research also is integral to the DIR mission, enabling key laboratory discoveries to be rapidly translated into methods to prevent, diagnose, or treat disease.

The NIDDK Intramural Research Program (IRP) is a component of NIDDK, whose mission is to conduct biomedical research and training related to diabetes mellitus; endocrine, bone, and metabolic diseases; digestive diseases, including liver diseases and nutritional disorders; and kidney, urologic, and hematologic diseases.

The Technology Transfer and Intellectual Property Office (TTIPO) at NIAID furthers NIAID's mission by fostering collaborations of NIAID scientists with partners in industry, academia, nonprofits, and other government agencies and facilitates the exchange of research materials and information.

The project should be relevant to the Institute's mission and likely to benefit (as measured by moving product development forward) small business concerns. Projects that fit within the NIAID or NIDDK mission on diagnostics and make use of these NIAID or NIDDK Intramural research inventions are eligible for this award.

This FOA applies to a number of diagnostic inventions originating from the NIAID intramural laboratories and one invention from NIDDK for which the US Government has various levels of patent protection. These include inventions that can be developed to detect the following infectious disease pathogens: Anthrax, dengue virus types 1-4, human immunodeficiency virus (HIV), Hepatitis A Virus (HAV), Hepatitis E Virus (HEV), lymphatic filariasis or negative strand RNA viruses (such as Ebola virus and Marburg virus). Inventions are also available that can be adapted for use in high throughput screening procedures to identify drugs to treat infectious diseases such as Human metapneumovirus, Hepatitis C Virus (HCV) or HEV. Outside the infectious diseases area, an additional invention may potentially be used in finding early cancers by detection of BORIS (Brother of Regulator of Imprinted Sites).

For more details on these inventions, please see a list of eligible inventions at the SBIR-TT NIAID Diagnostic page.

Applications that do not relate to the list of inventions mentioned above will not be considered responsive and will not be reviewed.

This FOA solicits applications focusing on collaborations with NIAID or NIDDK intramural scientists/inventors that address development of NIAID or NIDDK intramural diagnostic inventions. Applicants are **strongly encouraged** to contact the Scientific/Research Contact(s) prior to submitting any application. During the SBIR award period, an NIAID or NIDDK intramural investigator/inventor may provide assistance in a collaborative manner by providing, reagents and/or discussions. No SBIR funds may be used to support the NIAID or NIDDK intramural investigator or to support the NIAID or NIDDK intramural program. If collaboration with an intramural scientist/inventor

is not applicable, the SBC should explain this in the SBIR application.

If selected for SBIR funding the SBC will be granted a royalty-free, non-exclusive, internal research-use license to the United States Government’s intellectual property for the eligible inventions from the NIAID or NIDDK intramural programs, with the intent that the SBC will develop the technology into a commercial product to benefit the public, consistent with NIAID's and NIDDK’s missions. The license will be for the term of award and within the field of use of the SBIR award.

For more information please check The Small Business Innovation Research -Technology Transfer (SBIR-TT) FAQs page.